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# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference<br>58096 WO 003  | <b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA416) |  |
| International application No.<br>PCT/US 03/29356   | International filing date (day/month/year)<br>15.09.2003   | Priority date (day/month/year)<br>25.09.2002 |
| International Patent Classification (IPC) or both national classification and IPC<br>A61M15/00 |  |  |
| Applicant<br>3M INNOVATIVE PROPERTIES COMPANY et Al.   |  |  |

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 5 sheets, including this cover sheet.  
  
☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  
  
 These annexes consist of a total of    sheets.

- This report contains indications relating to the following items:
  - I    ☒ Basis of the opinion
  - II   ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV   ☐ Lack of unity of invention
  - V    ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI   ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application

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| Date of submission of the demand<br><br>15.04.2004  | Date of completion of this report<br><br>14.01.2005   |
| Name and mailing address of the international preliminary examining authority:<br><br> European Patent Office - P.B. 5818 Patentlaan 2<br>NL-2280 HV Rijswijk - Pays Bas<br>Tel. +31 70 340 - 2040 Tx: 31 651 epo nl<br>Fax: +31 70 340 - 3016 | Authorized Officer<br><br>Zeinstra, H<br><br>Telephone No. +31 70 340-2824<br><br> |

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/US 03/29356**

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-9 as originally filed

**Claims, Numbers**

1-6 as originally filed

**Drawings, Sheets**

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY  
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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

|                               |             |     |
|-------------------------------|-------------|-----|
| Novelty (N)                   | Yes: Claims |     |
|                               | No: Claims  | 1-6 |
| Inventive step (IS)           | Yes: Claims |     |
|                               | No: Claims  | 1-6 |
| Industrial applicability (IA) | Yes: Claims | 1-6 |
|                               | No: Claims  |     |

2. Citations and explanations

**see separate sheet**

**Re Item V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

- 1 Reference is made to the following documents:  
D1: Annales Françaises de Chronometrie et de Microtechnique, Observatoire de Besancon. Besancon, Fr (1998), 47, 115-121
- 2 Document D1 discloses (cf. the whole document)  
A breath actuated medicament dispensing device comprising:  
an aerosol container containing a pressurized medicament formulation equipped with a metered dose dispensing valve having a movable valve stem;  
a housing disposed about the aerosol container;  
a patient port in communication with the dispensing valve;  
priming means adapted to apply a bias to the valve stem relative to the aerosol container sufficient to move the valve stem to fire the valve;  
restraining means movable between a blocking position in which it prevents said bias firing the valve and a release position in which it allows said bias to fire the valve;  
trigger means responsive to inhalation through the patient port to cause the restraining means to move from its blocking position to its release position;  
wherein the aerosol valve comprises:  
a valve housing;  
a tank component positioned within the valve housing; and  
a valve stem mounted within said valve housing and tank component sequentially movable between a first position, a second position and a third position as the valve stem is depressed in a single direction;  
such that:  
as the valve stem is moved from said first position towards said second position a metering chamber is formed and defined between the valve stem and tank component and formulation flows from the aerosol container into the metering chamber;  
in said second position the metering chamber has a predetermined volume and is sealed from the aerosol container; and  
in said third position formulation is released from the metering chamber through the valve stem;

and wherein:

the priming means is constructed and arranged such that as the device is primed by operating said priming means the valve stem is moved from its first to its second position to allow formation and filling of the metering chamber;  
the restraining means is constructed and arranged such that in its blocking position it maintains the valve stem in its second position until the trigger means is actuated by inhalation through the patient port.

- 2.1 Thus, D1 discloses all the technical features of present independent claim 1. Therefore, the subject-matter of clarified claim 1 is not novel in respect to the prior art as defined in the regulations (Rule 64(1)-(3) PCT). Hence, the present application does not satisfy the criterion set forth in Article 33(2) PCT.
- 3 Dependent claims 2 to 6 do not appear to contain any additional features, which in combination with the features of any claim to which they refer, give rise to either novel subject-matter (Article 33(2) PCT) as all the features introduced with these claims seem to be known while used with a known corresponding effect.
- 3.1 In particular:
- the features of claims 2 to 6 are disclosed in combination with the features of claim 1 in D1 (cf. the whole document). Therefore the subject matter of claims 2 to 6 is not new.
- 4 The dispensing device of claims 1 to 6 is industrially applicable, and therefore the requirements of Article 33(4)PCT are met.